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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,793	01/11/2002	Victor Klimyuk	ICON-002	4086

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,793	KLIMYUK ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11-16,18,19,36-41,43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9,11-16,18,19,36-41,43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2152006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on March 7, 2006 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The specification cites Lee et al., J. Antibiot., 42:1970 (1989) on page 7, lines 20-21. This bibliographic citation is incorrect. Correction/clarification is required. New matter must be avoided.

Claim Rejections - 35 USC § 112

4. Claims 4, 43, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 4: the recitation, "said irradiating is a chemical agent" renders the claim indefinite. The specification does not define "irradiating" as encompassing any chemical agents, and chemical agents are not known in the art as a form of radiation.

In claim 43: part (e) recites, "fusing protoplasts containing the chromosome fragments from the cells of (d)". However, part (d) does not recite any steps in which protoplasts are produced. Step (d) results in cells, not protoplasts, which contain chromosome fragments.

5. Claims 19 remains and claims 4, 43, and 44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making plant protoplasts or cells or hybrid plant species comprising a plant artificial chromosome by irradiating protoplasts, does not reasonably provide enablement for the claimed methods by producing chromosome fragments in any other manner, or by producing chromosome fragments in plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record stated in the previous Office actions. Applicants traverse the rejection in the paper filed March 7, 2006. Applicants' arguments have been fully considered but were not found persuasive.

As discussed in the previous Office actions, claim 19 has been rejected because the specification fails to enable steps (b) and (c) of the claimed method, which require irradiating the transformed plants of part (a) to produce chromosome fragments, and crossing that plant with a second plant to produce hybrid plant species. Applicants argue that page 9, lines 11-21 teach each step of this process, and that this disclosure must be taken as in compliance with the

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enabling requirement of 35 U.S.C. 112, 1st paragraph, unless there is reason to doubt the objective truth of the statements. Applicants argue that the Examiner merely questioned whether a transformed plant can be crossed once it has been irradiated. Applicants argue that the passage on page 9 indicates that crosses between irradiated and normal plants can be done and result in transfer of market traits from the irradiated organism, and cite a single prior art reference published in 1975 (Pandey, Nature, Vol. 256, pages 310-313; response, paragraph bridging pages 7-8 to page 8, 1st full paragraph; a copy of the reference was provided in an IDS submitted March 7, 2006). Applicants also submitted a declaration under 37 CFR 1.132 executed by Dr. Victor Klimyuk, a co-inventor of the instant application. The declaration repeats the same argument (item 4).

It is noted that claim 19 requires irradiating plants, while Pandey teaches irradiating pollen. Amended claim 43 is included in this rejection, as step (d) encompasses irradiating cells, as opposed to protoplasts. The teachings of Pandey, which were conducted with *Nicotiana* species, have been questioned by those skilled in the art. Other researchers have not been able to reproduce the experiments of Pandey. Sanford et al. (Theor. Appl. Genet., 1984, Vol. 67, pages 553-558) were unable to reproduce the method taught by Pandey with tomato (pages 554-555). Chyi et al. (Theor. Appl. Genet., 1985, Vol. 70, pages 433-439) attempted to reproduce the experiments of Pandey, with *Nicotiana* species, including with stocks from the Pandey laboratory, and failed. Chyi et al. assert that other major research efforts have failed to extend Pandey's findings to other genera or to confirm his findings in *Nicotiana*, and conclude that observations of Pandey are not reproducible (abstract; page 439). Pandey (Theor. Appl. Genet., 1986, Vol. 72, pages 739-742) refutes the findings of Chyi et al. and provides alternative

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explanations. However, J.C. Sanford, (a co-author of Chyi et al.) provides a rebuttal in the same reference. It is apparent that, at the least, the teachings of Pandey (Nature, 1975) were not reduced to routine use in the art. Given the inability of others skilled in the art to reproduce the teachings of Pandey, and lack of further guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim 4 attempts to limit the irradiation step of the method of claim 1 by requiring it to be a chemical agent recited in a Markush group. It is unclear exactly how Applicants are intending to limit claim 1 (see the indefinite rejection above). However, if Applicants are attempting to limit the manner of producing chromosome fragments in the claimed method by using one of the recited chemical agents, rather than irradiation, the specification does not enable the claimed invention. The specification on page 7, lines 12-22, indicates that chromosome fragments may be produced in protoplasts or cells by treating or other contacting them with a chemical agent, examples being the chemicals recited in claim 4. The passage on page 7 indicates that the chemicals are believed to mediate chromosome cleavage via transient di-radical intermediates, and cites three prior art references. However, two of the references, Lee et al. (J. Am. Chem. Soc., 1992, vol. 114, pages 985-997) and Golik et al. (J. Am. Chem. Soc., 1987, Vol. 109, pages 3461-3462), do not teach anything about cleaving chromosomes within plant cells or protoplasts. The third, Lee et al. (page 7, lines 20-21) is an incorrect citation. The prior art teach does not teach any methodology, for example concentration of the chemicals, time of incubation, etc., for using any of the chemical agents to fragmentize chromosomes within plant cells or protoplasts such that they can be used in the claimed method. The specification does not cure the deficiencies of the prior art. Not only must the chromosomes be fragmentized, but also the

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claimed method requires the eventual recovery of fused protoplasts comprising chromosome fragments that exhibit normal plant chromosomal activities. In the absence of further guidance, undue experimentation would be required by one skilled in the art to develop a method of using any of the recited chemical agents to fragmentize chromosomes within plant protoplasts such that the treated protoplast can be recovered and fused with an untreated protoplast, and wherein the produced chromosome fragments retain all plant chromosome functions.

Claim Rejections - 35 USC § 103

6. Claims 1, 2, 5-9, 11-16, 18, 19, 36-41, 43, and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Famelaer et al. (Theor. Appl. Genet., 1990, Vol. 79, pages 513-520) in combination with Blume et al. (Plant Journal, 1997, Vol. 12, pages 731-746) and Adam et al. (Plant J., 1997, Vol. 11, pages 1349-1358), for the reasons of record stated in the previous Office actions. Applicants traverse the rejection in the paper filed March 7, 2006. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that neither Blume nor Adam teach or suggest employing the various plant transformation vectors taught therein, in conjunction with Famelaer's method specifically by using them to transform Famelaer's protoplasts prior to irradiation (response, page 9, 3rd full paragraph to the paragraph bridging pages 10-11). However, it is not necessary that a reference actually suggest changes that Applicants made. See *In re Sheckler*, 438 F.2d 999, 1001, 168 USPQ 716, 717 (CCPA 1971). The skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. Persons of ordinary skill in the art have a level of knowledge apart from the content of the references. *In re Bode*, 550 F.2d 656,

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660, 193 USPQ 12, 16 (CCPA 1977); *In re Jacoby*, 309 F.2d 513, 516, 135 USPQ 317, 319 (CCPA 1962). A conclusion of obviousness “from common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference” can be relied upon. *In re Bozek*, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). It was quite obvious that the protoplasts to be irradiated in the method of Famelaer could have been from a transgenic plant, and one would obviously have been motivated to use transgenic lines to introgress a desired trait conferred by a transgene into a desired recipient line.

Applicants argue that of Famelaer's R_1 generation, only two plants were almost normally self-fertile and reduced fertility was observed for progeny plants, and decreased transmission rates were observed with increasing fertility. Applicants conclude that Famelaer, by his own supposed admission, was unable to control or achieve consistent results with respect to chromosome transmission or normal chromosomal activity. Applicants conclude that the results were unpredictable (response, page 11, 1st full paragraph). However, Famelaer's supposed admission is actually Applicants' conclusion, not Famelaer's. Fertile hybrid plants were also obtained, and progeny analysis revealed a normalization of the transmission rate. Further, the instant claims do not mention anything concerning transmission rates. The instant specification states that by “normal chromosomal activity”, it is meant that minichromosomes, artificial chromosome or chromosome fragments contain a centromere, telomere and ARS sequences and are stable through normal cellular events such as meiosis and mitosis. That is, they are capable of independent replication and transmission through subsequent cell divisions (page 8, lines 3-7). That hybrid plants were regenerated and progeny thereof were obtained by Famelaer, shows that

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the chromosome fragments present in the treated protoplasts and plants of the reference meet these limitations.

Applicants also provide arguments in the declaration filed under 37 CFR 1.132, executed by Dr. Klimyuk. The declaration repeats the arguments discussed above (page 3, 2nd full paragraph). This argument is not found persuasive for the reasons discussed above. The declaration argue that absent any exogenous DNA present, there would be no reason to select for chromosome fragments that contain exogenous nucleic acid and which exhibit normal chromosomal activities (paragraph bridging pages 3-4). However, this argument considers the Famelaer reference in isolation, not in the combination with the other references.

7. Claims 1, 2, 4-9, 11-16, 18, 19, 36-41, 43, and 44 remain rejected. ‘

Contact Information

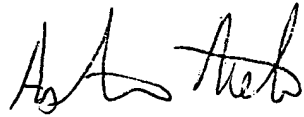
Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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May 26, 2006

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', written in a cursive style.

Ashwin D. Mehta, Ph.D.
Primary Examiner
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